

DOCKET NO.: ISIS-5468


PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Yogesh S. Sanghvi, et al.

Application No.: 10/828,659

Filing Date: April 21, 2004

For: PROCESSES FOR THE PREPARATION OF OLIGONUCLEOTIDES

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: *May 13, 2004*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

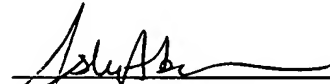
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1-35** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/640,279**, filed **August 16, 2000**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: May 13, 2004



Leslie E. Aberman
Registration No. 54,836

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. ISIS-5468	Application No. 10/828,659
		Applicant Yogesh S. Sanghvi, et al.	
		Filing Date April 21, 2004	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	1	Beaucage, S.L. et al., "The Synthesis of Modified Oligonucleotides by the Phosphoramidite Approach and their Applications", <i>Tetrahedron</i> , 1993 , <i>49</i> , 6123-6194	
	2	Cheruvallah, Z.S., et al., "Synthesis of antisense oligonucleotides: Replacement of 3H-1,2-benzodithiol-3-one 1, 1-dioxide (Beaucage Reagent) with phenylacetyl disulfide (PADS) as efficient sulfurization reagent: From bench to bulk manufacture of active pharmaceutical ingredient," <i>Organic Process Research & Development</i> , 2000 , <i>4</i> , 199-204	
	3	Cummings, A.D., et al., "Some observations with ultra-accelerators," <i>Ind. Eng. Chem.</i> , 1928 , <i>20(11)</i> , 1173-1176	
	4	Delgado, C., et al., "The uses and properties of PEG-linked proteins," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1992 , <i>9(3,4)</i> , 249-304	
	5	Efimov, V.A. et al., "New efficient sulfurizing reagents for the preparation of oligodeoxyribonucleotide phosphorothioate analogues", <i>Nucl. Acids Res.</i> , 1995 , <i>23</i> , 4029-4033	
	6	Eleueri, A., et al., "Pyridinium trifluoroacetate/ <i>N</i> -methylimidazole as an efficient activator for oligonucleotide synthesis via the phosphoramidite method," <i>Organic Process Res. & Dev.</i> , 2000 , <i>4</i> , 182-189	
	7	Eliel, E.L., et al., "Highly stereoselective syntheses involving <i>N</i> -alkyl-4,4,7 α -trimethyl- <i>trans</i> -octahydro-1,3-benzoxazine intermediates," <i>J. Org. Chem.</i> , 1990 , <i>55(7)</i> , 2114-2119	
	8	He, X-C. et al., "Highly Enantioselective Syntheses of α -Hydroxyacids Using <i>N</i> -Benzyl-4,4,7 α -Trimethyl- <i>Trans</i> -Octahydro-1,3-Benzoxazine as a Chiral Adjuvant," <i>Tetrahedron</i> , 1987 , <i>43(21)</i> , 4979-4987	
	9	Iyer, R.P. et al., "3H-1,2-Benzodithiole-3-one 1,1-Dioxide as an Improved Sulfurizing Reagent in the Solid-Phase Synthesis of Oligodeoxyribonucleoside Phosphorothioates", <i>J. Am. Chem. Soc.</i> , 1990 , <i>112</i> , 1253-1254	
	10	Iyer, R.P. et al., "The Automated Synthesis of Sulfur-Containing Oligodeoxyribonucleotides Using 3H-1,2-Benzodithiol-3-one 1,1-Dioxide as a Sulfur-Transfer Reagent", <i>J. Org. Chem.</i> , 1990 , <i>55</i> , 4693-4699	
EXAMINER		DATE CONSIDERED	



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. ISIS-5468	Application No. 10/828,659
		Applicant Yogesh S. Sanghvi, et al.	
		Filing Date April 21, 2004	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	11	Kamer, P.C.J. et al., "An Efficient Approach Toward the Synthesis of Phosphorothioate Diesters via the Schonberg Reaction", <i>Tetrahedron Letts.</i> , 1989 , 30, 6757-6760	
	12	Polushin, N. N. et al., "Synthesis of Oligonucleotides Containing 2'-Azido-and 2'-Amino-2'-deoxyuridine Using Phosphotriester Chemistry," <i>Tetrahedron Letts.</i> , 1996 , 37(19), 3227-3230	
	13	Rao, M.V., et al., "Solid phase synthesis of phosphorothioate oligonucleotides using benzyltriethylammonium tetrathiomolybdate as a rapid sulfur transfer reagent," <i>Tetrahedron Lett.</i> , 1994 , 35(36), 6741-6744	
	14	Rao, M.V. et al., "Dibenzoyl Tetrasulphide-A Rapid Sulphur Transfer Agent in the Synthesis of Phosphorothioate Analogues of Oligonucleotides", <i>Tetrahedron Letts.</i> , 1992 , 33, 4839-4842	
	15	Roclen, H. et al., "A study on the use of phenylacetyl disulfide in the solid-phase synthesis of oligodeoxynucleoside phosphorothioates," <i>Recl. Trav. Chim. Pays-Bas</i> , 1991 , 110, 325-331	
	16	Stec, W.J. et al., "Bis (O,O-Diisopropoxy Phosphinothiyl) Disulfide - A Highly Efficient Sulfurizing Reagent for Cost-Effective Synthesis of Oligo(Nucleoside Phosphorothioate)s", <i>Tetrahedron Letts.</i> , 1993 , 34(33), 5317-5320	
	17	Tang, J., et al., "Large-scale synthesis of oligonucleotide phosphorothioates using 3-amino-1,2,4-dithiazole-5-thione as an efficient sulfur-transfer reagent," <i>Organic Proc. Res. & Dev.</i> , 2000 , 4, 194-198	
	18	Vu, H., et al., "Internucleotide phosphite sulfurization with tetraethylthiuram disulfide. Phosphorothioate oligonucleotides synthesis via phosphoramidite chemistry," <i>Tetrahedron Lett.</i> , 1991 , 32(26), 3005-3008	
	19	Xu, Q. et al., "Use of 1,2,4-dithiazolidine (DtsNH) and 3-ethoxy-1,2,4-dithiazoline-5-one (EDITH) for synthesis of phosphorothioate-containing oligodeoxyribonucleotides", <i>Nucl. Acids Res.</i> , 1996 , 24(9), 1602-1607	
	20	Xu, Q. et al., "Efficient introduction of phosphorothioates into RNA oligonucleotides by 3-ethoxy-1,2,4-dithiazoline-5-one (EDITH)", <i>Nucl. Acids Res.</i> , 1996 , 24, 3643-3644	
EXAMINER		DATE CONSIDERED	



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. ISIS-5468		Application No. 10/828,659	
	Applicant Yogesh S. Sanghvi, et al.			
	Filing Date April 21, 2004		Group Not Yet Assigned	
	Confirmation No. Not Yet Assigned			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	21	Zhang, Z., et al., "Solid phase synthesis of oligonucleotide phosphorothioate analogues using bis(ethoxythiocarbonyl)tetrasulfide as a new sulfur-transfer reagent," <i>Tetrahedron Lett.</i> , 1998 , 39, 2467-2470		
	22	Zhang, Z., et al., "Solid phase synthesis of oligonucleotide phosphorothioate analogues using 3-methyl-1,2,4-dithiazolin-5-one (MEDITH) as a new sulfur-transfer reagent," <i>Tetrahedron Lett.</i> , 1999 , 40, 2095-2098		
EXAMINER		DATE CONSIDERED		



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. ISIS-5468	Application No. 10/828,659
	Applicant Yogesh S. Sanghvi, et al.	
	Filing Date April 21, 2004	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	23	4,458,066	07/03/84	Caruthers, et al.	536	27
	24	4,816,571	03/28/89	Andrus, et al.	536	27
	25	5,149,798	09/22/92	Agrawal, et al.	536	27
	26	5,166,387	11/24/92	Hirschbein	558	129
	27	5,386,023	01/31/95	Sanghvi, et al.	536	25.3
	28	5,424,184	06/13/95	Santamaria, et al.	435	6
	29	5,614,621	03/25/97	Ravikumar, et al.	536	25.34
	30	5,750,666	05/12/98	Caruthers, et al.	536	23.1
	31	5,859,221	01/12/99	Cook, et al.	536	23.1
	32	6,025,482	02/15/00	Cook, et al.	536	23.1
	33	6,399,765 B1	06/04/02	Krotz, et al.	536	25.31
	34	6,653,458 B1	11/25/03	Manoharan, et al.	536	23.1

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	35	WO 93/07883	04/29/93	PCT		

EXAMINER	DATE CONSIDERED
-----------------	------------------------